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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,940	09/09/2003	Jason D. Meridew	5490-000341	1613
27572 7590 12/26/2007 HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			EXAMINER SHAFFER, RICHARD R	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 12/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/657,940	Applicant(s) MERIDEW ET AL.	
	Examiner Richard R. Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10,12,16-21 and 23-45 is/are pending in the application.
- 4a) Of the above claim(s) 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10,12,16-21,23-38 and 40-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The amendments to the claims filed on October 15th, 2007 are acknowledged and accepted by the examiner. The previous 35 U.S.C. 112, first and second paragraph rejections are hereby withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the limitation "the slot" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

The amendments to the claims filed on October 15th, 2007 are acknowledged and accepted by the examiner. The previous 35 U.S.C. 101 rejections are hereby withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-8, 16-19, 32-38 and 40-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Kohrs et al (US Patent 6,224,631).

Kohrs et al disclose a cylindrical, resorbable (**Column 3, Lines 40-47**) implant/bone screw (**10, Figure 1**) having a threaded (**7**) exterior; a pair of opposed channels (**24a/b**); disposing graft material inside the screw; **[First Interpretation]** a driver (**506, Figures 16 and 17**) also having a threaded/cutting portion (**526, 527**) and a driving portion (508 or the abutment surface between the threaded prongs); a U-shaped (has a curvature similar to a U) fastener (**40, Figure 1**) also having threads (**43**) and configured to be disposed within the channels. The fastener and implant define an aperture there between (**9a/b/c**).

[Second Interpretation] a staple (**506, Figures 16 and 17**) an aperture is inherent between the abutment/graft holding surface (between prongs) of the staple and the surface of the bone screw (**10**) should soft tissue pass through (soft tissue is not positively recited). The staple is inherently interrupts the arcuate groove of the threaded exterior and is inherently capable of being offset to prevent rotation of the implant (and is offset numerous times during insertion and removal).

Kohrs et al further disclose a method

[First Interpretation] of forming an aperture within a bone; channels (**24a/b**) in an exterior surface of the implant (**10**); coupling the implant to a driver (**506**); driving the implant into the aperture; forming an implant engaging surface within the aperture; and coupling soft tissue to the implant (inherent) because the body is full of soft tissue, the device is clearly indirectly coupled to soft tissue located elsewhere in the body.

[Second Interpretation] of forming an aperture within a bone; driving a threaded implant (10) into a bone aperture; the threads of the implant (10) define arcuate grooves between them; inserting a staple (506) into a slot defined in the threaded surface, whereby the staple bindingly intersects the groove and engages both the implant and bone aperture; and interposing a graft between the implant and a surface defining the staple (additional graft material may be inserted inside the additional passages of implant (10)). During insertion and removal of the staple, the grooves are intersected thereby preventing rotation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 10, 12, 20, 21 and 23-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Jackson (US Patent 6,835,206) in view of Jackson (US Patent 6,440,170).

Jackson '206 discloses a system (**Figures 1-7**) comprising:

[First Interpretation] an exterior threaded implant (10) having an anchor locking surface (32); a driver (74, 75 and 76 together) with a cutting portion (76) and a driving portion (74 and 75); and a staple (83) having an upward locking surface (81).

[Second Interpretation] an exterior threaded implant (10 and 11 together) having an anchor locking surface (42); a driver (71-76 together) with a cutting portion (76) and a

driving portion (74 and 75); and a staple (12, 13 and 14 together, Figure 1) having an upward locking surface which engages anchor locking surface (42); and a graft interposed between the staple and implant (Column 8, Line 65 through Column 9, Line 14).

Jackson '206 further discloses a method (Figure 5) comprising: forming an implant engaging surface within bone by rotating a driver (71); driving a threaded (31) implant (10); and inserting a staple (83) into two longitudinal channels thereby intersecting the grooves (during insertion and removal and therefore preventing rotation) defined by the threading of implant (10).

Jackson '206 discloses all of the claimed limitations except for a pair of longitudinal channels formed on the screw, the staple/driver being inserted within the channels and the bone screw being made of resorbable materials.

Jackson '170 teaches (Figures 1-7) a screw implant with concave sides thereby defining two longitudinal channels to receive tools for insertion. It would have been obvious to one having ordinary skill in the art to substitute the straight/flat sides of Jackson '206 with the concave sides of Jackson '170 in order to provide for an interface between the screw implant and insertion tools with predictable results.

It would have further been obvious to one having ordinary skill in the art at the time the invention was made to use a bioabsorbable material since it has been held that such is within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments filed October 15th, 2007 have been fully considered but they are not persuasive.

In regard to Kohrs et al, applicant contends that the newly added limitation of the fastener and implant define an aperture there-between, it was explained in the current Office Action that windows 9a/b/c can be interpreted as apertures between the fastener and implant.

Applicant also continues to argue in most claims (including those rejected by Jackson '206) that the references do not disclose the ability of staple interpretations to intersect the arcuate groove and prevent rotation. As repeatedly stated in the current Office Action, the devices do indeed intersect during insertion and removal and even if they did not, they are inherently capable of as long as their respective threading is offset from the other as stated in the previous Office Action. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

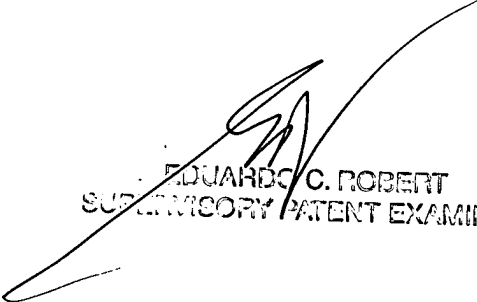
Application/Control Number:
10/657,940
Art Unit: 3733

Page 8

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Richard Shaffer
December 16th, 2007



EDWARD C. ROBERT
SUPERVISORY PATENT EXAMINER